

**COMMITTEE ON GOVERNMENT REFORM**  
**TOM DAVIS, CHAIRMAN**



**MEDIA ADVISORY**

**For Immediate Release**  
**March 16, 2004**

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**Government Reform Committee to Address**  
**Growing Sale of Prescription Drugs Online**

*Will Review Need for Bipartisan Legislation To Protect Consumers*

**What: Government Reform Committee oversight hearing:**  
**“A Prescription for Safety: The Need for H.R. 3880,**  
**The Internet Pharmacy Consumer Protection Act”**

**When: MARCH 18, 2004, 10:00 A.M. [immediately following brief business meeting]**

**Where: ROOM 2154, RAYBURN HOUSE OFFICE BUILDING**

**Background:**

This hearing will focus on the need for H.R. 3880, the “Internet Pharmacy Consumer Protection Act,” which would counter the growing sale of prescription drugs over the Internet without a valid prescription. Introduced by Chairman Tom Davis and Minority Ranking Member Henry Waxman, the legislation would amend the Federal Food, Drug, and Cosmetic Act to address this problem in three steps.

First, the bill establishes new disclosure standards for Internet pharmacy websites. Internet pharmacies are required to display information identifying the business, pharmacist, and physician associated with the website.

Second, H.R. 3880 stipulates an “appropriate medical relationship” must exist prior to the selling or dispensing of prescription drugs over the Internet. The bill prohibits Internet pharmacy sites from selling or dispensing prescription drugs to consumers who are provided a prescription solely on the basis of an online questionnaire. A prescription drug may not be sold or dispensed if the doctor has not had at least one in-person consultation with the patient.

Third, the bill provides additional enforcement authority to take action against illegal Internet pharmacies. This provision, modeled after the Federal Telemarketing Sales Act, will allow a state attorney general to file an injunction in federal court to shut

down a rogue site across the country, rather than only bar sales to consumers of his or her state.

Additionally, H.R. 3880 is intended to counter domestic Internet pharmacies that sell drugs without a valid prescription, not international pharmacies that sell drugs at a low cost to individuals who have a valid prescription from their U.S. doctors.

“The illegal diversion and abuse of prescription drugs is becoming an increasingly serious problem. While I normally believe that the federal government should play a minimal role in regulating on-line commerce, this legislation is necessary because too many Americans, especially teenagers, are finding ways to gain access to potentially deadly prescription drugs without valid prescriptions. Up to this point, regulating these Internet pharmacies has been a challenge for federal and state enforcement capabilities,” Chairman Davis said.

The sale of consumer products over the Internet has grown exponentially over the past 10 years. Access to prescription drugs via online pharmacies can provide potential benefits to consumers, including convenience and reduced costs. While many online pharmacies operate in the same manner as traditional brick-and-mortar drug stores, and comply with the standards of state licensing authorities, not all pharmacies practicing over the Internet are legitimate sites. The Internet creates an easy environment for illegitimate sites to bypass traditional regulations and established safeguards for the sale of prescription drugs.

Public health and consumer safety issues arise when the sale of prescription drugs occur without a valid prescription or adequate physician supervision. Although the Federal Food, Drug, and Cosmetic Act requires that prescription drugs be dispensed only upon receipt of a valid prescription (section 503), it is now easy to obtain virtually any medication online without ever seeing or speaking with a physician. This absence of a doctor-patient relationship does not meet the appropriate standard of care dictated by state medical boards.

Purchasing drugs online is simple: a consumer just types the name of the drug into a search engine, quickly identifies a site selling the medication, and then clicks to purchase. On some sites, the consumer must fill out a health questionnaire to be reviewed by a physician prior to the prescription. However, use of these online questionnaires allows consumers to manipulate their medical history in order to be approved for the drug they desire. On other sites, no questionnaire is even required. The web site operator typically contracts with a physician who is paid for every prescription written.

A brief online interaction, even if a questionnaire is used, may miss essential information on whether a given drug is safe for a particular patient. The risks of self-medicating can include potential adverse reactions from inappropriately prescribed medications, dangerous drug interactions, and use of counterfeit or tainted products. Several of these illegitimate sites fail to provide information about contraindications, potential adverse effects, and efficacy.

Regulating these Internet pharmacies can be a challenge for Federal and state enforcement capabilities. Not all Internet pharmacies comply with state licensing requirements and standards. Authorities have trouble tracking down these illegitimate sites because many do not disclose identifying information, change their names and appearances often, and sometimes disappear without a trace. Accountability becomes problematic when the violators cannot be identified and located.

State medical and pharmacy boards have expressed concern that they do not have adequate enforcement tools to regulate practice over the Internet. It can be virtually impossible for states to identify, investigate, and prosecute these illegal pharmacies because the consumer, prescriber, and seller of a drug may be located in different states.

In support of the legislation, Dr. James Thompson, President and CEO of the Federation of State Medical Boards (FSMB), stated, "It is possible to define the physician-patient relationship narrowly, solely for the purpose of enforcing a federal law regulating Internet pharmacies, without affecting the autonomy of state boards to regulate the practice of medicine."

John Rector, General Counsel of the National Community Pharmacists Association (NCPA), said, "The legislation will help deter unlawful use of the internet and consequently, consumers are far more likely to receive lawfully prescribed prescription drugs and related pharmacists services from legitimate properly licensed pharmacies and trustworthy pharmacists."

The Committee will hear testimony from the following witnesses:

**William Hubbard**, Senior Associate Commissioner for Policy Planning and Legislation  
Food and Drug Administration

**James Thompson**, M.D., President and Chief Executive Officer  
Federation of State Medical Boards

**Carmen Catizone**, M.S., R.Ph., D.Ph., Executive Director  
National Association of Boards of Pharmacy

**TBD**, National Association of Attorneys General

**Rebecca J. Patchin**, M.D., Trustee  
American Medical Association

**John M. Rector**, Senior Vice President of Governmental Affairs and General Counsel  
National Community Pharmacists Association

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